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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,867	01/21/2000	Michael J. Imperiale	11203-002001	5039
20985	7590	05/19/2004	EXAMINER	
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/488,867	IMPERIALE, MICHAEL J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 March 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,10,11,13,14,17,20-27,31-33,35,40,41,43 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 1-5,10,11,17,35,40 and 41 is/are allowed.  
 6) Claim(s) 13,14,31,32,33 is/are rejected.  
 7) Claim(s) 20-27 and 43 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_.  
 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

**Non-Final Rejection**

Claims 1-5, 10, 11, 13, 14, 17, 20-27, 31-33, 35, 40, 41, and 43 are pending.

Applicant's traversal, the amendment to claims 1, 3, 13, 17, 23, 26, 27, 31, 32, 33, 40, and 41, the addition of claim 43, and the amendment to the specification filed on 3/17/04 is acknowledged and considered.

Upon further consideration, the indicated allowability of claims 20-27 is withdrawn in view of the newly discovered objections. Objections follow.

*Claim Objections*

Claim 20 is objected to because of the following informalities: there is a first adenovirus serotype-specific cis-acting packaging sequence, but no second cis-acting sequence. There is a second adenovirus serotype specific 52/55 kDa protein, but no first 52/55 kDa protein. Claims 23-25 recite a second adenovirus serotype sequence and depend from claim 20.

Claims 21, 22, and 26 are objected to because the claims depend from claim 20.

Suggest deleting "second" in line 1 of step (b) and inserting:

-- is specific for a second adenovirus serotype specific cis-acting packaging sequence and -- between "protein" and "is not specific" in line 2 of step (b) of claim 20.

Appropriate correction is required.

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Claim 23 is objected to because of the following informalities: the phrase “sequence are selected from the group consisting of” on line 3 is grammatically incorrect.

Suggest amending the phrase to recite -- sequence are selected from an adenovirus from the group consisting of --.

Appropriate correction is required.

Claim 23 is also objected to because of the following informalities: the phrase “sequence is from a different serotype than the second adenovirus” on lines 5-6 is grammatically incorrect.

Suggest amending the phrase to recite -- sequence is from an adenovirus of a different serotype than the second adenovirus --.

Appropriate correction is required.

Claims 24 and 25 are objected to because of the following informalities: the phrase “wherein the first adenovirus serotype is adenovirus type.. and the second adenovirus serotype sequence is adenovirus type.. .” is grammatically incorrect.

Suggest amending the phrase to recite -- wherein the first adenovirus serotype is from adenovirus type. and the second adenovirus serotype sequence is from adenovirus type.. . --

Appropriate correction is required.

Claims 27 and 43 are objected to because of the following informalities: the phrase “adenovirus encapsidated” on lines 1-2 is grammatically incorrect.

Suggest amending the phrase to recite: -- encapsidated adenovirus --.

Claims 31-33 are objected to because of the following informalities: the phrase “a replication defective encapsidated adenovirus vector” on line 1 is grammatically incorrect. Suggest amending the phrase to recite: -- an encapsidated replication defective adenovirus vector --.

In addition, the phrase “transforming or infecting...host cell” step a) for claim 31 is grammatically incorrect.

Suggest amending step (a) to recite: -- transforming or infecting adenovirus replication competent host cells with... --.

In addition, the phrase “host cell a first and second adenovirus replication defective sequences” on lines 3 and 4, step (a) of claim 32 is grammatically incorrect.

Suggest amending step a) to recite: -- transforming or infecting adenovirus replication competent host cells with...--.

In addition, step (a) lines 1-2 claims 33 is grammatically incorrect. Suggest amending step (a) to recite: -- transforming or infecting adenovirus replication competent host cells with...--.

Suggest amending step a) to recite: -- transforming or infecting adenovirus replication competent host cells with a first and second adenovirus replication defective sequence --.

Claim 31 is also objected to because of the following informalities: the phrase “protein specific for a first adenovirus” step (iii) lines 20-21 is grammatically incorrect.

Suggest amending the phrase to recite: -- protein specific for the first adenovirus --.

Claim 32 is also objected to because of the following informalities: the phrase “packaging of a first adenovirus nucleic acid sequence and fails to support the packaging of a second adenovirus serotype-specific cis-acting packaging sequence” lines 5-6 is grammatically incorrect.

Suggest amending the phrase to recite: -- packaging of the first adenovirus nucleic acid sequence and fails to support the packaging of the second adenovirus serotype-specific cis-acting packaging sequence, but not the second cis-acting packaging sequence --.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 13, 14, and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a

gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between “an adenovirus replication competent host cell” in step (c) of claim 1 and “an adenovirus replication competent host cell containing the vector system” on the last line of claim 13.

Claim 14 is also rejected because it is dependent on claim 13.

Suggest replacing the phrase “an adenovirus replication competent host cell containing the vector system” in the last line of claim 13 with the phrase -- the adenovirus replication competent host cell --

In addition, suggest inserting the term -- the -- before the phrase “adenovirus replication competent host cell” in claim 14.

Claims 31, 32, and 33 recite the limitation "the cells" in first line of step (b). There is insufficient antecedent basis for this limitation in the claim.

Suggest making cell plural in step (a), line 1 of claims as suggested under the objection for claims 31, 32, and 33.

#### ***Response to Arguments***

Applicant’s arguments, filed 3/17/04, with respect to objection have been fully considered and are persuasive. The objection to the hyperlink in the specification has been withdrawn because of the amendment to the specification.

Applicant’s arguments, filed 3/17/04, with respect to 112 first paragraph written description rejection have been fully considered and are persuasive. The rejection of claims 1, 2,

3, 4, 5, 6, 7, 8, 10, 11, 13, 14, 26 and 17 has been withdrawn because of the amendment to the claims to recite a cell comprising a nucleic acid encoding an adenovirus 52/55 kDa trans-acting protein.

Applicant's arguments, filed 3/17/04, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 14, 15, 18, 19, 23, 24, 25, 26, 27, 31, 32, 33, 34, 40, 41 and 42 has been withdrawn because of the amendment to the claims and the cancellation of claims 6-9, 12, 15, 18, 19, 34, and 42. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claims 13, 14, 31, 32, and 33.

Applicant's arguments, filed 3/17/04, with respect to provisional nonstatutory double patenting rejection have been fully considered and are persuasive. The rejection of claims 17, 19, and 42 has been withdrawn because of the amendment to the claims and the cancellation of claims 19 and 42 and the amendment to claim 17.

### ***Conclusion***

Claims 1-5, 10, 11, 17, 35, 40, and 41 are in condition for allowance because the claims are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Brian Whiteman  
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER